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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,633	11/20/2006	Salvatore Avolio	ITT0061P	2568
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 12/14/2007		EXAMINER LOEWE, SUN JAE Y	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,633	Applicant(s) AVOLIO ET AL.	
	Examiner Sun Jae Y. Loewe	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 13-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is a national stage application of PCT/GB04/04306. Claims 1-10 and 13-19 are pending in the instant application. Claims 11 and 12 were cancelled by preliminary amendment filed on April 7, 2006.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-10, 13 and 14 drawn to products of Formula I wherein $X1=CRa$; $X2=CR1$; $X3=CR2$; $X4=CRb$; $A1=cyclohexyl$; one of $R1$ or $R2$ is carboxy; $Ar1=Ar=phenyl$. Further election of a single compound is required.
- II. Group II, claim(s) 1-10, 13 and 14 drawn to products of Formula I wherein $X1=CRa$; $X2=CR1$; $X3=CR2$; $X4=CRb$; $A1=cyclohexyl$; one of $R1$ or $R2$ is carboxy; one of $Ar1$ or $Ar=thiazolyl$. Further election of a single compound is required.
- III. Group III, claim(s) 1-10, 13 and 14 drawn to products of Formula I wherein $X1=CRa$; $X2=CR1$; $X3=CR2$; $X4=CRb$; $A1=cyclohexyl$; one of $R1$ or $R2$ is carboxy; one of $Ar1$ or $Ar=pyridinyl$. Further election of a single compound is required.
- IV. Group IV, claim(s) 1-10, 13 and 14 drawn to products of Formula I wherein $X1=CRa$; $X2=CR1$; $X3=CR2$; $X4=CRb$; $A1=cyclohexyl$; one of $R1$ or $R2$ is carboxy; one of $Ar1$ or $Ar=imidazolyl$. Further election of a single compound is required.

- V. Group V, claims(s) 1-10, 13 and 14 drawn to products of Formula I not covered by Groups I-IV. Further election of a single compound is required. Further restriction may apply.
- VI. Group VI, claim(s) claims 15 and 19 drawn to method of using products of Group I. Further election of a single compound is required.
- VII. Group VII, claim(s) claims 15 and 19 drawn to method of using products of Group II. Further election of a single compound is required.
- VIII. Group VIII, claim(s) claims 15 and 19 drawn to method of using products of Group III. Further election of a single compound is required.
- IX. Group IX, claim(s) claims 15 and 19 drawn to method of using products of Group IV. Further election of a single compound is required.
- X. Group X, claim(s) claims 15 and 19 drawn to method of using products of Group V. Further election of a single compound is required.
- XI. Group XI, claim(s) claims 16 and 17 drawn to method of making products of Group I by reaction of compounds of Formulae IV and V. Further election of a single compound of Formula I is required.
- XII. Group XII, claim(s) claims 16 and 17 drawn to method of making products of Group II by reaction of compounds of Formulae IV and V. Further election of a single compound of Formula I is required.
- XIII. Group XIII, claim(s) claims 16 and 17 drawn to method of making products of Group III by reaction of compounds of Formulae IV and V. Further election of a single compound of Formula I is required.
- XIV. Group XIV, claim(s) claims 16 and 17 drawn to method of making products of Group IV by reaction of compounds of Formulae IV and V. Further election of a single compound of Formula I is required.

- XV. Group XV, claim(s) claims 16 and 17 drawn to method of making products of Group V by reaction of compounds of Formulae IV and V. Further election of a single compound of Formula I is required.
- XVI. Group XVI, claim(s) claims 16 and 17 drawn to method of making products of Group I by reaction of compound of Formula V. Further election of a single compound of Formula I is required.
- XVII. Group XVII, claim(s) claims 16 and 17 drawn to method of making products of Group II by reaction of compound of Formula V. Further election of a single compound of Formula I is required.
- XVIII. Group XVII, claim(s) claims 16 and 17 drawn to method of making products of Group III by reaction of compound of Formula V. Further election of a single compound of Formula I is required.
- XIX. Group XIX, claim(s) claims 16 and 17 drawn to method of making products of Group IV by reaction of compound of Formula V. Further election of a single compound of Formula I is required.
- XX. Group XX, claim(s) claims 16 and 17 drawn to method of making products of Group V by reaction of compound of Formula V. Further election of a single compound of Formula I is required.

3. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature linking the subject matter of Groups I-X is a fused pyrrole . All other structural features are variables, and thus do not constitute a linking technical feature. This core structure is taught in the prior art, eg. see p.41 of WO 03/010140.

4. This application contains Markush claims directed to more than one species. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: compounds encompassed by Formula I obtained by varying the substituents to the core structure.

Applicant is required, in reply to this action, to elect a single species within the elected group to which the claims shall be restricted if no Markush claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a Markush claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed Markush claim (MPEP 803.02). If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner: claims 1-10 and 13-19 encompass species described in section 4.

6. The species described within section 4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the reason provided in section 3.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074.

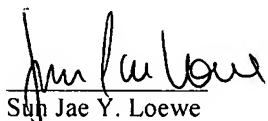
The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sun Jae Y. Loewe
Patent Examiner
Art Unit 1626

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